



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Ear, Nose, and Throat Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Ear, Nose, and Throat Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 30 and May 1, 2015 from 8 a.m. to 6 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301-977-8900.

Contact Person: Patricio Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1535, Silver Spring MD 20993-0002, Patricio.Garcia@fda.hhs.gov, 301-796-6875, or FDA Advisory Committee

Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice.

Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On April 30, 2015, the committee will discuss and make recommendations regarding the classification of Hearing Protectors, Circumaural Hearing Protectors, Middle Ear Inflation Devices, Tactile Hearing Aid Devices, and Vestibular Analysis Apparatuses. These devices are considered preamendments devices since they were in commercial distribution prior to May 28, 1976, when the Medical Devices Amendments became effective. Hearing Protectors are currently regulated under the heading, "Protector, Hearing (Insert)," Product Code EWD, as unclassified under the 510(k) premarket notification authority. Circumaural Hearing Protectors are currently regulated under the heading, "Protector, Hearing (Circumaural)," Product Code EWE, as unclassified under the 510(k) premarket notification authority. Middle Ear Inflation Devices are currently regulated under the heading, "Device, Inflation, Middle Ear," Product Code MJV, as unclassified under the 510(k) premarket notification authority. Tactile Hearing Aid Devices are currently regulated under the heading, "Hearing Aid, Tactile," Product Code LRA, as unclassified under the 510(k) premarket notification authority. Vestibular Analysis Apparatuses are currently regulated under the heading, "Apparatus, Vestibular Analysis," Product Code LXV, as unclassified under the 510(k) premarket notification authority. FDA is seeking committee input on the risks, safety and effectiveness and the regulatory classification of Hearing Protectors,

Circumaural Hearing Protectors, Middle Ear Inflation Devices, Tactile Hearing Aid Devices, and Vestibular Analysis Apparatuses.

On May 1, 2015 the committee will discuss key issues related to a potential pre- to post-market shift in clinical data requirements for modifications to cochlear implants in pediatric patients. These issues are categorized into three broad areas for discussion:

1. Cochlear implant changes (e.g. sound processing features, patient characteristics) that may be suitable for this pre- to post-market shift in clinical data requirements.
2. Appropriate premarket clinical data requirements to support pre- to post-market shift (e.g. leveraging clinical data from adults and/or older children.)
3. Clinical study design considerations (e.g. study endpoints and test metrics, subject characteristics) for post market studies to confirm safety and effectiveness and inform future labeling.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before April 22, 2015. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:45 a.m. on April 30, 2015 and between approximately 1

p.m. and 2 p.m. on May 1, 2015. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 14, 2015. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 16, 2015.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact at James Clark at James.Clark@fda.hhs.gov, or 301-796-5293 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 9, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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